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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,847	12/05/2003	William Alston	0138.00	8316

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NEKTAR THERAPEUTICS
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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,847	ALSTON, WILLIAM	
	Examiner	Art Unit	
	Shumaya B. Ali	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action*.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2,3,5,7,8,10-13,15,17,18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niccolai US Patent 6,705,313 in view of Dean et al. US Patent No. 4,249,526

2. As to claim 1, Niccolai discloses an aerosolization apparatus comprising: a body **(see col.2 line 50)** defining an inlet opening **(where reference object 13 is situated),** an outlet opening **(toward the mouthpiece, see col.1 line 19)**, and an aerosolization chamber **(see fig.1 reference object 17)** between the inlet opening and the outlet opening, wherein the aerosolization chamber is adapted to receive an elongated receptacle **(see fig.1 reference object 18)** containing a pharmaceutical formulation **(receptacle is a fine powder contained capsule, see col.1 lines 7-8, and additionally a capsule inherently contain pharmaceutical formulation, this case in the form of powder)** and wherein the elongated receptacle rotates (see col.3 lines 24-28), an axis **(parallel to the longitudinal axis of the apparatus), however does not disclose** end-over-end about an axis substantially orthogonal to an axis passing through the

outlet opening when air or gas flows through the body. **However, Dean et al. teach the underlined limitation in figure 2, where Dean et al. teach an inhalation device where a capsule (receptacle) is caused to rotate about its 2-fold axis of symmetry (end-on-end) allowing medicament to escape and entrained before inhalation (see col.4 lines 32-38). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the device of Niccolai in view of Dean et al. in order allow a receptacle to move about its 2 fold axis or symmetry or end on end for the purposes of allowing medicament to escape and entrained before inhalation.**

3. **As to claim 2, Niccolai discloses** an aerosolization apparatus according to claim 1 further comprising an opening mechanism **(see fig.1 reference objects 15)** for creating an opening in the receptacle.

4. **As to claim 3, Niccolai discloses** an aerosolization apparatus according to claim 2 wherein the opening mechanism comprises a sharpened tip **(see col.3 lines 11-12)** moveable (translatable) **(see col.3 lines 11-14)** within the aerosolization chamber.

5. **As to claim 5, Niccolai discloses** an aerosolization apparatus according to claim 4 wherein the receptacle comprises a capsule **(see col.3 line 20).**

6. **As to claim 7, Niccolai discloses** an aerosolization apparatus according to claim 5 wherein the receptacle contains a powder pharmaceutical formulation **(see col.1 lines 7-8)**.

7. **As to claim 8, Niccolai does not disclose** an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 um. **A close review of the applicant's discloser reveals "a particle size selected to permit penetration into the alveoli of the lungs" (see specification page 14, lines 26-27). The mass median diameter will vary depending on the releasing site/the type of tissue absorbing that medication.**

Mass median diameter can be made smaller or larger to respectively increase or decrease the absorbent nature of the tissue. Therefore, it would have been obvious to one of ordinary skills in the art while preparing the pharmaceutical formulation particles for an asthma patient with a mass median diameter smaller for the purposes of increasing the absorbent efficiency of the lung tissue to rapidly reduce possible breathing difficulties experienced a user.

8. **As to claim 10, Niccolai discloses** an aerosolization apparatus for delivering an aerosolized pharmaceutical formulation to a user's respiratory tract, the apparatus comprising: a body **(see col.2 line 50)** defining an inlet opening **(where reference object 13 is situated)**, an outlet opening **(toward the mouthpiece, see col.1 line 19)**, and an aerosolization chamber **(see fig.1 reference object 17)** between the inlet opening and the outlet opening, wherein the aerosolization chamber is adapted to receive an elongated receptacle **(see fig.1 reference object 18)** containing a pharmaceutical formulation **(receptacle is a fine powder contained capsule, see col.1 lines 7-8, and additionally a capsule inherently contain pharmaceutical formulation, this case in the form of powder)**, an axis **(parallel to the longitudinal axis of the apparatus) however does not disclose** wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis parallel to an inhalation direction when the user inhales to cause air or gas to pass through the body. **However, Dean et al. teach the underlined limitation in figure 2, where Dean et al. teach an inhalation device where a capsule (receptacle) is caused to rotate about its 2-fold axis of symmetry (end-on-end) allowing medicament to escape and entrained before inhalation (see col.4 lines 32-38). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the device of Niccolai in view of Dean et al. in order allow a receptacle to move about its 2 fold axis or symmetry or end on end for the purposes of allowing medicament to escape and entrained before inhalation.**

9. **As to claim 11, Niccolai discloses** an aerosolization apparatus according to claim 10 wherein the inhalation direction is a direction coincident with an axis passing through a mouthpiece **(see col.1 line 19)** of the apparatus.

10. **As to claim 12, Niccolai discloses** an aerosolization apparatus according to claim 10 further comprising an opening mechanism **(see fig.1 reference objects 15)** for creating an opening in the receptacle.

11. **As to claim 13, Niccolai discloses** an aerosolization apparatus according to claim 12 wherein the opening mechanism comprises a sharpened tip **(see col.3 lines 11-12)** moveable (translatable) **(see col.3 lines 11-14)** within the aerosolization chamber.

12. **As to claim 15, Niccolai disclose** an aerosolization apparatus according to claim 14 wherein the receptacle comprises a capsule **(see col.3 line 20).**

13. **As to claim 17, Niccolai disclose** an aerosolization apparatus according to claim 15 wherein the receptacle contains a powder pharmaceutical formulation **(see col.1 lines 7-8)**.

14. **As to claim 18, Niccolai does not disclose** an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 um. **A close review of the applicant's discloser reveals "a particle size selected to permit penetration into the alveoli of the lungs" (see specification page 14, lines 26-27). The mass median diameter will vary depending on the releasing site/the type of tissue absorbing that medication. Mass median diameter can be made smaller or larger to respectively increase or decrease the absorbent nature of the tissue. Therefore, it would have been obvious to one of ordinary skills in the art while preparing the pharmaceutical formulation particles for an asthma patient with a mass**

median diameter smaller for the purposes of increasing the absorbent efficiency of the lung tissue to rapidly reduce possible breathing difficulties experienced a user.

15. **As to claim 20, Niccolai disclose** an aerosolization apparatus according to claim 10 wherein the inlet opening is shaped to cause a swirling air or gas flow **(see col.3 lines 44-48)** through the chamber.

Claims 6,9,16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niccolai US Patent 6,705,313 and Dean et al. US Patent No. 4,249,526 and in view of Chiprich et al. US Patent 5,614,217

16. **As to claim 6, Niccolai does not disclose** an aerosolization apparatus according to claim 5 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxyproplycellulose, and agar. **As to claim 6, Chiprich et al. teach capsule wall composition of gelatin and cellulose/starch contents (see col.2 lines 55-68 and col.3 lines 1-18) providing a vehicle for dispensing pre-measured medicaments (see col.3 lines 29-30). Also teach the biodegradable nature of the gelatin capsule provides for consumer acceptance of disposable products. Since the capsules as taught by Chiprich contain a non-hygroscopic plasticizer, they require less moisture resistance in their packaging than traditional soft gelatin capsules and therefore provide cost efficiency because of less expensive packaging materials being required (see col.3 lines 38-45). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to add gelatin and cellulose contents to the wall of Niccolai in view of Chiprich for the purposes of creating a medicine dispensing vehicle that requires less moisture resistance in their packaging than traditional soft gelatin capsules, therefore further providing cost efficiency because of less expensive packing materials.**

17. **As to claim 9, Niccolai does not disclose** an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation has moisture content below 5% by weight. **A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in the prior art (see specification page 15, lines 2-4). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established criticalities between a moisture content of 10% or 3% by weight. As to claim 9, Chiprich et al. teach, a brittle gelatin capsule comprises about 5-15% water by weight. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Niccolai in view of Chiprich in order to provide a moisture content of 5-15% since it is well known in the art that a low water content is advantageously used in the process of making a powder-like medicine for the purposes of increasing the drying process of the powder.**

18. **As to claim 16, Niccolai does not disclose** An aerosolization apparatus according to claim 15 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxyproplycellulose, and agar. **As to claim 16, Chiprich et al. teach capsule wall composition of gelatin and cellulose/starch contents (see col.2 lines 55-68 and col.3 lines 1-18) providing a vehicle for dispensing pre-measured medicaments (see col.3 lines 29-30). Also teach the biodegradable nature of the gelatin capsule provides for consumer acceptance of disposable products. Since the capsules as taught by Chiprich contain a non-hygroscopic plasticizer, they require less moisture resistance in their packaging than traditional soft gelatin capsules and therefore provide cost efficiency because of**

less expensive packaging materials being required (see col.3 lines 38-45). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to add gelatin and cellulose contents to the wall of Niccolai in view of Chiprich for the purposes of creating a medicine dispensing vehicle that requires less moisture resistance in their packaging than traditional soft gelatin capsules, therefore further providing cost efficiency because of less expensive packing materials.

19. **As to claim 19, Niccolai does not disclose** An aerosolization apparatus according to claim 17 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 gm. An aerosolization apparatus according to claim 17 wherein the powder pharmaceutical formulation has moisture content below 5% by weight. **A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in the prior art (see specification page 15, lines 2-4). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established criticalities between a moisture content of 10% or 3% by weight. As to claim 19, Chiprich et al. teach, a brittle gelatin capsule comprises about 5-15% water by weight. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Niccolai in view of Chiprich in order to provide a moisture content of 5-15% since it is well known in the art that a low water content is advantageously used in the process of making a powder-like medicine for the purposes of increasing the drying process of the powder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shumaya B. Ali
Examiner
Art Unit 3743

11/7/06

Henry Bennett
Supervisory Patent Examiner
Group 3700